UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	Magistrate Judge Marianne B. Bowler

UNITED STATES' REPLY TO ABBOTT LABORATORIES INC.'S MEMORANDUM IN OPPOSITION TO THE UNITED STATES' MOTION FOR PARTIAL SUMMARY JUDGMENT, AND SUR-REPLY TO ABBOTT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

There is no dispute that Abbott reported drug prices that bore no relationship to its costs or actual market prices. The evidence uncovered in this case shows that such efforts were part of Abbott's scheme to game the health care reimbursement system for its own pecuniary gain. For Abbott to prevail, it must convince the Court that the Health Care Financing Administration (HCFA) knew the market prices of Abbott's drugs, yet intentionally chose to reimburse providers based on false prices. Current and former Medicare and Medicaid officials testified that: 1) HCFA wanted to fairly and accurately reimburse providers for the estimated acquisition cost of drugs; 2) HCFA relied upon the accuracy of the manufacturers' reporting to the compendia to assist it; and 3) HCFA had no policy or practice to deliberately use inflated AWPs to reimburse providers for drug ingredient costs to make up for inadequate dispensing fees.[1]

Abbott must also further convince this Court that Abbott itself relied on purported government approval when it reported its false prices. The multiple, resource-intensive audits and investigations of manufacturers' internal workings conducted by government agencies were all trying to get to the bottom of a problem, not trumpeting the success of manufacturer driven mega-spreads. Thus, they clearly would undercut any claim of reliance (were any evidence of reliance actually offered.) Leaving that aside, however, Abbott's own lobbying efforts demonstrate that Abbott never believed that HCFA approved of its false prices. Instead, Abbott feared that if the reimbursement formula was changed, HCFA would reduce reimbursement for its drugs.

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[1] *See* United States' common reply memorandum of law in support of its cross-motions for partial summary judgment and sur-reply in opposition to the defendants' motions for summary judgment ("U.S. Common Reply Brief") that addresses the key common arguments made in Abbott's Opposition/Reply and is incorporated by reference. In this reply to Abbott's individual brief in opposition to the United States' Motion for Summary Judgment (Dkts. 6440; 416) ("U.S. Abbott Opposition/Reply"), the United States will focus on a few discrete issues.

Far from being an innocent bystander confused about the meaning or role of AWP in the Medicare and Medicaid programs, Abbott ignored the government's repeated inquiries and investigation, and vigorously lobbied against changes to the AWP-based reimbursement system. (US-A-SF ¶¶ 111-113)[2] The undisputed evidence also reveals that Abbott's HPD Home Infusion business unit directly and knowingly submitted false claims to Medicare and Medicaid on its own behalf and on behalf of its revenue share partners. Such evidence under the False Claims Act warrants partial summary judgment in favor of the United States, and a denial of Abbott's motion for partial summary judgment.

ARGUMENT

I. Abbott Submitted False Prices and Reaped the Benefits of Its Own Mega-Spreads

Abbott does not dispute that it never reported its actual prices to the United States. Nor does Abbott claim that it sought, let alone *obtained*, approval for its price setting and price reporting conduct. (US-A-SF ¶¶ 105-110) Abbott also does not dispute the following: 1) it reported to the compendia only its very highest prices, which it charged less than one-half of one percent of the time; 2) the difference between the reimbursement and the average of the wholesale prices for the Subject Drugs resulted in spreads of between 113 and 1685 percent,[3] thereby establishing the falsity of Abbott's price reporting; and 3) it never informed HCFA that the reported list prices that were used to calculate its AWPs bore no predictable relation to its costs or actual market prices. (US-A-SF ¶¶ 105-113, 123, 147) Abbott readily admits that its

[2] References to ("US-A-SF ¶ __ ") are to the United States' Amended Statement of Facts in the Abbott case (Dkts. 6322; 326). References to ("US Resp. ABT SOAF ¶ __") are to the United States' Responses to Abbott's Rule 56.1 Statement of Additional Facts.

[3] Notably, for all of the facts and exhibits it submitted, Abbott does not provide an alternative range for what it believed its spreads to be.

HPD pricing was not predicated upon any reliance on government reports – or anything else dealing with Medicaid or Medicare, including a desire to cross-subsidize. (ABT-SOAF ¶ 74; US-A-SF ¶ 40)

Not surprisingly, Abbott attempts to diminish the significance of its HPD Home Infusion business unit, which directly benefitted from the spreads since it submitted claims to the Medicare and Medicaid programs. However, based upon evidence from Abbott's own computer claims data, from 1991 to 2001, Abbott's HPD Home Infusion business unit directly billed over $1.7 billion to and was paid over $660 million by all types of third party payors. Of that total, claims to Medicare and Medicaid that included at least one of the Subject Drugs accounted for $232 million in billings and over $45 million paid to Abbott. (US Resp. ABT SOAF ¶ 15; US-A-SF ¶¶ 132-146) Abbott knew or should have known that its HPD Home Infusion profits were derived, at least in part, from the spreads paid by Medicare and Medicaid on the Subject Drugs, just like other pharmacy and physician customers.

II. Abbott Alone Is Responsible For Its Conduct

A. Abbott Controlled Its AWPs

Abbott's first line of attack on the United States' summary judgment motion is to deny responsibility for its reported AWPs, claiming that because it only reported its highest public catalog prices to the compendia – not AWPs – it is not responsible for the published AWPs. Abbott argues that its list prices were truthful by pointing to a few actual sales made at those high list prices. Characterizing list price as a formulaic equivalent to AWP, this Court already has rejected this form over substance argument, holding Bristol Myers Squibb (BMS) accountable for unfair and deceptive trade practices where the list price submitted by BMS and used in calculating AWP no longer reflected the price generally and currently paid. *See In re Pharm.*

Indus. AWP Litig., 491 F. Supp. 2d 20, 104-105 (D. Mass. 2007). In Abbott's case, its list prices for the Subject Drugs were its very highest prices and represented less than one-half of one percent of its sales. (US-A-SF ¶¶ 29, 61-62) Abbott's list prices were thus the direct opposite of prices generally and currently paid.

Furthermore, as a factual matter, it is clear that Abbott was well aware that its list price reporting was the causal link to the calculation of its AWPs by the compendia. In 2001, Jerrie Cicerale, an Abbott employee responsible for HPD's price *reporting* to the compendia, explained to her boss, Harry Adams, who in turn was largely responsible for *setting* HPD's list prices, her 20-year belief that the First Databank AWP was "a calculation from our direct (list) price. . .". (US Resp. ABT SOAF ¶ 42)

Abbott knew the impact of its list price changes upon published AWPs when it raised and lowered its Vancomycin list price in 1995. (US-A-SF ¶¶ 71-81) Further, Abbott's HPD HBS Operating Procedures manual even detailed the actual 18.75% markup formula used by First Databank. (US-A-SF ¶ 104) Finally, the research Abbott engaged in prior to its 2001 price reductions reflects Abbott's understanding that its list prices and the resulting AWPs were tied to the profits of its Alternate Site business unit, the unit within Abbott HBS responsible for sales to providers in non-hospital settings, such as long-term care facilities, home infusion pharmacies, and surgery centers. Before lowering the list prices, Michael Sellers, Director of Contract Marketing for Abbott HBS, undertook an almost 5-month evaluation of how such reductions would affect the bottom line, and actually projected the resulting lost profits. (US-A-SF ¶¶ 60-63; US Resp. ABT SOAF ¶ 75) There is simply no dispute that Abbott's reported prices caused the resulting published AWPs and that Abbott was fully cognizant of the link.

There is also no dispute that, with rare exception, all states paid on the basis of Estimated Acquisition Cost (EAC) for all drugs when it resulted in lower reimbursement and, notwithstanding the testimony presented by the defense, these states would have paid and did pay lower reimbursement for the Subject Drugs when the defendants reported lower prices. In opposing summary judgment, Abbott offers no evidence to dispute or disprove that Medicare and Medicaid paid lower reimbursement on the Subject Drugs after Abbott lowered its HPD prices in 2001.

B. Abbott's Purported Lack of Knowledge Qualifies as Reckless Disregard At A Minimum

Abbott contends there was no uniform understanding of AWP within Abbott, and that it did not understand that its reported prices needed to be in line with its wholesale market prices. The difficulty with this argument is that another division within Abbott apparently did report truthful list prices. Abbott does not dispute that its Pharmaceutical Products Division (PPD) appropriately set its reported list prices at a small percentage above its wholesale prices. Abbott's brief fails to explain why for nearly all of its PPD products, it elected to play by the rules, but flouted the rules for its HPD products. Looking at the evidence in the light most favorable to Abbott, even if *arguendo* HPD HBS employees were "in the dark," Abbott's conduct constitutes reckless disregard, at a minimum, because the Abbott employees "in the know" about AWP turned a blind eye to the damage caused by HBS's list price reporting. At the same time that Abbott is claiming its employees effectively did not know the law and did not understand the potential harm to government health care programs, Abbott Home Infusion

enjoyed profits resulting from inflated Medicare and Medicaid reimbursement. (US-A-SF ¶¶ 119-145)[4]

Abbott also seeks to shift blame to third parties by claiming that HPD was told *by the compendia* to report its highest prices as its list prices. Notably, Abbott offers no correspondence, emails, meeting notes or third party testimony from the compendia to corroborate its story for the 1991 to 2001 time period. Abbott's sole employee witness for this point only generally explains his "understanding" of these alleged compendia instructions, without any detail as to their content, time frame or context. (US Resp. ABT SOAF ¶ 48)

Abbott's own communications to and from First Databank's Kaye Morgan belie Abbott's story. First Databank was under the impression that HPD's reported list prices were the equivalent of its WACs. In emails to Jerrie Cicerale, Ms. Morgan made clear First Databank's historic requirement that Abbott's reported list (direct) prices correlate to Abbott's wholesale

[4] Furthermore, the HPD Alternate Site Vice-President, Don Robertson, explained the significance of AWPs to the division president as early as 1991. (US-A-SF ¶ 55) In addition, Abbott's in-house counsel was actively involved in AWP and price reporting issues, including entering an appearance in litigation and writing a brief for Abbott's joint venture TAP in 1997, seeking to keep TAP's Lupron AWP in place for Medicare reimbursement purposes. (US-A-SF ¶¶ 130, 131) Abbott admits that its in-house attorneys were responsible for its Medicare, Medicaid and FCA compliance, and in fact advised HPD employees regarding the same. (US-A-SF ¶¶ 126-128) Contrary to Abbott's assertion that this Court has determined the TAP case irrelevant, this Court has recognized the relevance of Abbott's role in TAP AWP-related matters when it ordered: "TAP shall produce all documents expressly referencing Abbott or directly involving Abbott personnel" relating to AWP/government reimbursement issues or AWP spread marketing from 1991 to 2003. (Dkt. 4701) Further, the fact that Abbott's joint venturer, TAP, pled guilty and entered into a corporate integrity agreement with the government for, among other acts, marketing the spread, should inform the Court's decision-making on issues related to Abbott's purported lack of understanding of AWP and the impact of its price reporting conduct. As a condition of resolving TAP's criminal and civil liability, Abbott was a required signatory to a letter agreement consenting to TAP's criminal, civil and administrative resolutions. (US-A-SF ¶ 131)

prices.[5] First Databank's understanding, as articulated by Ms. Morgan, was consistent with the undisputed fact that nearly all of Abbott's PPD reported list prices were pegged by Abbott at their WAC prices, plus a 5% mark-up. HPD, in fact, adopted this WAC-plus 5% formula in drastically lowering its list prices in 2001. (US-A-SF ¶ 56-70)[6] In any event, the compendia were not responsible for ensuring Abbott's compliance with Medicare, Medicaid or the FCA – Abbott was.

C. Abbott's Own Experts and Its Past Lobbying Debunk the Claim of Government Approval

Finally, Abbott contends that its inflated price reporting was condoned as an unarticulated, non-public "policy choice" by HCFA. As part of its efforts to pursue this theme, Abbott retained a former state Medicaid official and a former federal official, both of whom testified to the contrary. Abbott expert Louis Rossiter, a former Virginia Secretary of Health and Human Resources, testified that he would never have accepted drug companies' inflated price reporting to manipulate the spread on Virginia Medicaid reimbursement. (US Resp. ABT SOAF ¶ 89)

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[5] Ms. Morgan wrote: "AWP stands for AVERAGE WHOLESALE PRICE – it is the price from the wholesaler. As long as WAC and Direct were equal, it does not matter whether we were using WAC or Direct. . . . [W]e cannot use Direct to determine AWP if it is different." She then wrote in that same email chain: "Let me reiterate what I [said] below. AWP is AVERAGE WHOLESALE PRICE. We [First Databank] determine AWP by contacting the wholesalers for the mark-up. As long as your direct [list] was equal to WAC life was fine." (US Resp. ABT SOAF ¶ 48).

[6] Recently, the First Circuit, relying upon this Court's prior order, and using almost verbatim language, recognized the history of AWP as a price rooted in real, transactional wholesale pricing, emphasizing that the reported AWP is usually derived by applying a multiplier to the WAC for the drug. *National Assn. of Chain Drug Stores v. New England Carpenters Health Benefits Fund*, — F.3d —, 2009 WL 2824867, at *1 & n.2 (1st Cir., Sept. 3, 2009).

Another Abbott expert, Robert Helms, the former Assistant Secretary of the United States Department of Health and Human Services (HHS), confirmed his understanding that Medicaid's "estimated acquisition cost" regulation requirement meant the best estimate of the price generally and currently paid in the market place. (US Resp. ABT SOAF ¶ 89) Professor Helms also confirmed that the EAC requirement was a check and balance intended to protect the federal and state public fisc. (US Resp. ABT SOAF ¶ 89) More significantly, Professor Helms confirmed that he and others in positions of authority did not believe drug manufacturers would manipulate and inflate price reports. (US Resp. ABT SOAF ¶ 89) Even by the testimony of Abbott's own experts, this hardly sounds like government acquiescence, much less knowing approval of Abbott's conduct.

This Court is well versed in the history of the legislation impacting AWP and Medicare and Medicaid reimbursement, and the inclusion of the 95% of AWP language in the Balanced Budget Act of 1997 (BBA). *See In re Pharm. Indus. AWP Litig.*, 491 F. Supp. 2d at 41-44. What the Court is unaware of, since Abbott failed to disclose the information, is that Abbott vigorously lobbied against the inclusion of any language in the BBA affording discretion to the HHS Secretary to lower Medicare reimbursement. Abbott's efforts are a direct rebuke to its claim now that it believed HCFA approved of inflated price reporting in order to address other policy goals.[7] In deciding whether its CEO should lobby directly on the issue, Abbott's lobbyist wrote, "[t]he downside [to Mr. Burnham's lobbying activities] is Duane being exposed to having

[7] Abbott, among other defendants, had previously asserted and lost these positions in *In re: Lupron Marketing & Sales Practices*, 295 F. Supp. 2d 148, 162-163 (D. Mass. 2003). The *Lupron* court soundly rejected Abbott's earlier arguments that: a) government regulators' recognition of inefficiencies in Medicare equates to government condonation of fraud; and, b) by passing the BBA, Congress "turn[ed] a blind eye to the inflated AWPs as a means of enticing physicians to treat Medicare patients". *Id.* at 162-163, 168-169 & n.19.

to defend our position *which is profit motivated. There is no way to avoid that fact*." (US Resp. ABT SOAF ¶ 82) (St. Peter-Griffith Decl. Ex. 12 (Abbott Case Pltfs. Ex. 1138)) (emphasis added).

Abbott lobbyist and Medicare Working Group member, David Landsidle, stressed Abbott's imperative interest in a "solution" that did not allow discretion to the Secretary. (US Resp. ABT SOAF ¶ 82) (St. Peter-Griffith Decl. Ex. 12 (Landsidle 10/15/07 Dep. 230:9-22; 230:3-5)) In a June 5, 1997 memo, Mr. Landsidle urged: "Congress should not permit HHS to determine reimbursement rates drug by drug." (US Resp. ABT SOAF ¶ 82) (St. Peter-Griffith Decl. Ex. 12 (Landsidle Dep. Ex. 21)) If Abbott truly believed that HCFA approved of its inflated prices, why would Abbott fear drug by drug reimbursement rates? Moreover, why would it so stridently oppose the Secretary's discretion in setting reimbursement? In fact, Abbott knew that inflated AWPs – for cross-subsidization or any other purpose – were not a "policy choice" ever made by HCFA. *See In re Pharm. Indus. AWP Litig.*, 491 F. Supp. 2d at 94-95.

III. Abbott Home Infusion Conduct Relates Back to Ven-A-Care's Original Complaint

Abbott does not, and cannot, deny that its HPD Home Infusion business unit directly billed third party payors over one billion dollars on behalf of itself and its customers from 1991 to 2001. Indeed, Abbott's damages are unchanged as these claims were already part of the predicate claims for the Ven-A-Care complaint. For the $232 million in claims directed to Medicare and Medicaid, Abbott caused the submission under the FCA by directly submitting the false claims, which is the exact same conduct and transactions set forth in Ven-A-Care's complaint. Outside the context of this unit, Abbott nonetheless caused other providers to submit false claims to Medicare and Medicaid. In both instances, the United States has a cause of action against Abbott under the FCA. 31 U.S.C. § 3729(a)(1). Abbott attempts to make this factual

distinction between the claims processes of its separate HPD units a legal dispute by claiming that it cannot be liable under both theories. Even under Fed. R. Civ. P. 15(c), the allegations pass muster.

CONCLUSION

Abbott is solely responsible for its own price setting and reporting conduct, which violated the False Claims Act. Its motion for partial summary judgment, therefore, should be denied, and partial summary judgment should be granted in favor of the United States.

Respectfully submitted

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "United States' Reply to Abbott Laboratories Inc.'s Memorandum in Opposition to the United States' Motion for Partial Summary Judgment, and Sur-reply to Abbott's Motion for Partial Summary Judgment" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Mark Lavine

Dated: September 22, 2009 Mark Lavine